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TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER
817.1013PCT

U.S. APPLICATION NO the known see 37 C.E.R. 1.5

INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE PRIORITY DATE CLAIMED PCT/US2004/000273 6 January 2004 6 January 2004 TITLE OF INVENTION **NIGHT-TIME ORAL INSULIN THERAPY** APPLICANT(S) FOR DO/EO/US Michael GOLDBERG and Ehud ARBIT Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: This is a FIRST submission of items concerning a filing under 35 U.S.C. 371. This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371. X This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items 3. (5), (6), (9) and (21) indicated below. The US has been elected (Article 31). A copy of the International Application as filed (35 U.S.C. 371(c)(2)) is attached hereto (required only if not communicated by the International Bureau). As been communicated by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US). An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). is attached hereto. has been previously submitted under 35 U.S.C. 154(d)(4). Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) are attached hereto (required only if not communicated by the International Bureau). have been communicated by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. have not been made and will not be made. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). Items 11 to 20 below concern document(s) or information included: 11. An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. A preliminary amendment. 14. An Application Datasheet under 37 CFR 1.76. A substitute specification. A power of attorney and/or change of address letter. 17. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825. 18. A second copy of the published international application under 35 U.S.C. 154(d)(4). 19. A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). 20. Other items or information:

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PTO-1390 (Rev. 2-2005)
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23. Search fee Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the										١٧
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Additional fee for specification and drawings filed in paper over 100 sheets (excluding							 * *	-		
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The fee is \$250 for each additional 50 sheets of paper or fraction thereof.							ł			
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50 - 100 =	/50	=			x \$250	=	\$0	.00		
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e))+							\$			
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Total Claims		39 - 20 =	19	×	\$50	=	\$ 9	50.00		
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MULTIPLE DE	PENDENT CL	AIM(S) (if applica	ble)	+	\$360	+	\$			
TOTAL OF ABOVE CALCULATIONS =							\$ 1	650.00		
Applicant claims small entity status. See 37 C.F.R. 1.27. Fees above are reduced							· · · · · · · · · · · · · · · · · · ·			
by ½. – SUBTOTAL =							\$ 1650.00			
Processing fee of \$130.00 for furnishing the English translation later than 30 months from							H	\$		
the earliest claimed priority date (37 CFR 1.492(f)). + TOTAL NATIONAL FEE =							L_	\$ 1650.00		
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Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +							\$			
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a. A check in the amount of \$ to cover the above fees is enclosed.										
b. Please charge my Deposit Account No. <u>50-0552</u> in the amount of \$ <u>1650.00</u> to cover the above fees. A duplicate copy of this sheet is enclosed.										
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			er 37 CFR 1.494 o			met, a	peti	tion to revive (37	7 CFR 1.137(a) or	
(b)) must be filed and granted to restore the application to pending status. SEND ALL CORRESPONDENCE TO:										
Davidson, Davidson & Kappel, LLC SIGNATURE							W			
485 Seventh Avenue, 14th Floor										
New York, NY 10018 (212)-736-1940					Morey B. Wildes NAME					
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Re.: Docket No.: 817.1013US

Applicant(s): Michael GOLDBERG, et al.

Serial No.: To Be Assigned

Invention: NIGHT-TIME ORAL INSULIN THERAPY

Filing Date: Herewith

- Transmittal Letter to the US DO/EO re filing under 35 U.S.C. 371 (2 pages);
- Copy of Published International Application No. PCT/US2004/000273 (51 pages);
- International Search Report (3 pages);
- Information Disclosure Statement (1 page) and Form PTO-1449 (1 page);
- Written Opinion of the Int'l Searching Authority (5 pages);
- Preliminary Amendment (8 pages); and
- Application Data Sheet (2 pages).

This collection of information is required by 37 CFR 1.10. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.8 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.